



**Center for Women
Policy Studies**

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January 26, 2006

Andrew C. von Eschenbach, MD
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Building, Room 14-71
Rockville, MD 20857

Dear Dr. von Eschenbach:

I am writing to add my voice to those of my colleagues from other women's organizations to ask you to attend to an important women's health issue that warrants immediate FDA action – the possibly illegal manufacturing and marketing of bio-identical hormones.

We understand that certain compounding pharmacies have created a large market for bio-identical hormone replacement therapy (BHRT) products by using celebrities and making misleading and unsubstantiated claims about the benefits and risks of these products. Such claims suggest that these products have fewer side effects compared to FDA-approved therapies, that they offer protection against heart disease, reduce breast cancer risk, and decrease the risk of Alzheimer's disease and colorectal cancer. I know that you and your scientific colleagues will agree that FDA cannot allow such unsubstantiated claims to stand.

Some of the bio-identical hormone replacement therapy compounding practices appear to violate one or more of the principles outlined in FDA's own Compliance Policy Guide for pharmacy compounding. For example, FDA might be able to take action against the illegal production of BHRT products based on the fact that some of these products include estriol, which is not a component in any FDA-approved therapy. Furthermore, an argument can be made that these pharmacies are producing BHRT products "that are essentially copies of commercially available, FDA-approved drug products," also in violation of the Compliance Policy Guide. If FDA confirms that a pharmacy's compounding activities rise to the level of drug manufacturing, then the agency must take prompt regulatory action.

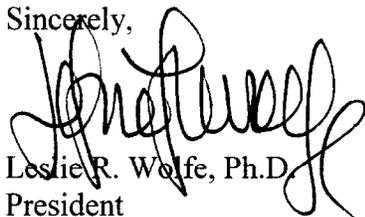
Of course we are concerned when women are exposed to unknown health risks – in this case, from unregulated BHRT products that FDA has the ability and mandate to control.

2005P-0411

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We urge you to protect women's health by exercising FDA's authority by ensuring that compounding pharmacies are in compliance with the law.

Sincerely,

A handwritten signature in black ink, appearing to read 'Leslie Wolfe', written over the printed name and title.

Leslie R. Wolfe, Ph.D.
President

cc: Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852
RE: Docket Number 2005P-0411